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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,057	01/31/2002	Michael B. Zemel	UTR-104D1	8306
26694	7590	07/25/2005	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998			WEBMAN, EDWARD J	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 07/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/066,057	Applicant(s) ZEMEL ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6 and 27-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 27-61 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Prosecution is reopened in view of a new rejection based on an admission by one of the inventors.

Claims 1, 4-6, 27-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those on a low-calorie diet and who are not already consuming three servings of dairy, does not reasonably provide enablement for on any diet and consuming any amount of dairy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The "Express," a daily tabloid published by the Washington Post, is cited as extrinsic evidence containing an admission by one of the inventors, Michael Zemel. In an article on page 10 of the 7/19/05 issue he is cited as stating that the claimed invention works only for people who eat a low-calorie diet and who are not already consuming three servings of dairy.

Applicants' claims do not recite such limitations. Applicants are advised that such an amendment to the claims must be supported by the specification.

Claim 51 is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Nowhere in the specification do applicants provide evidence that the claimed method can prevent weight gain. Further, no parameters against which the claimed effect of prevention can be tested, such as the length of time that the effect is manifest after treatment, are provided. That is, applicants do not provide a definition as to what they intend by the term "preventing".

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One of ordinary skill in the art would not find prevention of weight gain by the claimed method believable on its face because weight loss is deemed a complex process.

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In view of the rejection over utility above, wherein the claimed method is inoperable, the claimed method necessarily lacks enablement.

Claims 1, 4-6, 27-60 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. On page 10 of the above cited article from the Express published on 7/19/05, Dr. Walter Willet, a Harvard University nutrition expert, is cited as stating that the studies of Michael Zemel supporting the claimed method are too small and that larger randomized trials do not show a weight loss, but rather a weight gain. Thus, it appears that the claimed method is inoperative.

Claims 1, 4-6, 27-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In view of the rejection over utility above, wherein the claimed method is inoperable, the claimed method necessarily lacks enablement.


No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500**